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MAY 1 6 2001

II. 510(k) Summary

Submitted by: Active Corporation
15 Main Street
PO Box 1000
Castine, ME 04421
207-326-9100

Contact Person: Karen Siegel

Date Prepared: February 20, 2001

Proprietary Name: ActiveECG™

Common Name: Cardiac Monitor

Classification Name: Electrocardiograph (21 CFR §870.2300)

Predicate Device: Pam Cardiac Monitor
510(k) # K 934684

Description of the Device: ActiveECG is an electrocardiograph monitoring device used to record and collect ECG data using three electrodes. ActiveECG can display the ECG signal on an off-the-shelf Palm OS handheld, transfer the ECG data to a Windows compatible PC, and display, notate and print or forward a report using the accompanying ActiveECG Viewer software for Windows.

Intended Use of the Device: ActiveECG is intended to be used for the recording, displaying and reviewing of ECG signals with the purpose of analyzing cardiac rhythms and performing quick patient assessments.

Technological Characteristics: ActiveECG has the same basic technological characteristics as the predicate device. ActiveECG was designed utilizing the industry recognized standards, EC13, EC38, ES1 and the FDA Recognized Standard EN 60601-1-2. ActiveECG is similar to the predicate device in that it records, and displays ECG data in a portable environment. ActiveECG differs from this device as it is smaller and lighter than the predicate device, uses standard off-the-shelf non-rechargeable batteries, and provides greatly extended battery life through sophisticated power management. In addition, ActiveECG utilizes an off-the-shelf Palm OS handheld for its display device rather than an integrated display. These differences do not effect safety and effectiveness of the device as demonstrated by conformance to the above standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2001

Ms. Karen Siegel
Active Corporation
15 Main Street
P.O. Box 1000
Castine, ME 04421

Re: K010587
Trade Name: ActiveECG
Regulation Number: 870.2300
Regulatory Class: II (two)
Product Code: 74 DRT
Dated: February 24, 2001
Received: February 27, 2001

Dear Ms. Siegel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

X. Indications for Use Statement

510(k) Number: ~~Not Known~~ K010587

Device Name: ActiveECG Cardiac Monitor

Indications for Use:

ActiveECG is intended to be used for the recording, displaying and reviewing of ECG signals with the purpose of analyzing cardiac rhythms and performing quick patient assessments.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010587

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR §801.109)

[redacted]
Active Corporation